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Intramedullary v/s plate fixation for clavicle fractures: A systematic review

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Abstract
Objective: The purpose of this literature review was to evaluate intramedullary (IM) nailing as a technique for clavicle fracture fixation as compared to traditional plate fixation.
Methods: A search of the current literature was performed, leading to the inclusion of 38 suitable papers for analysis. A search on EMbase conducted using the search items "intramedullary nail" and "clavicle" was performed. The outcomes of these papers were used to outline a better understanding of the role of IM nailing in the treatment of displaced clavicle fractures, especially those involving the midshaft of the bone.
Results/Discussions: Each fixation method is not without complication, but both modalities can be used successfully in a range of settings, when operative management is pursued. Surgeon preference and expertise largely dictates the choice of treatment for displaced midshaft clavicle fractures.
Conclusion: From this systematic review, it is possible to suggest that both intramedullary fixation and plate fixation have very positive results in terms of shoulder function scores, as well as time to union.

Keywords: intramedullary nail, clavicle, fracture, plate fixation, union, function

Introduction
Clavicle fractures are a common upper limb injury associated with athletic and non-sporting endeavours. Typically, clavicle fractures occur due to falls from height, sporting trauma and direct impact injuries. The clavicle, due to its unique morphology, can fracture at several points along its curvature [1]. Traditionally, treatment has been non-operative and supportive [2] but operative management with either plating or intramedullary nailing (IM) has been also used for specific indications, namely, lateral third fractures and displaced (100%) mid-shaft fractures or those with more than 2cm of shortening. This review aims to assess intramedullary fixation as an operative technique for mid-shaft clavicle fractures. It will also attempt to compare it to other fixation methods in terms of effectiveness, pain, return to function and subsequent sequelae by evaluating literature, retrospective and prospective trials and case series.

Methods
In order to evaluate IM nailing as a technique for clavicle fracture fixation a search of the literature was undertaken. A search on EMbase conducted using the search items "intramedullary nail" and "clavicle", with results limited to "English", "human studies" and published between 2010 and 2016 was undertaken. Of this, 38 studies were identified as suitable. A review of the titles and abstracts of the studies revealed 18 appropriate studies. These studies also included links to three studies that were outside of the required time frame, which have been included in this review. Several studies were excluded, including paediatric and adolescent studies, as well as case reports, and documentation of conference abstracts, oral or poster presentations, which are not considered acceptable standards of evidence upon which to base clinical decision making in Orthopaedics. As a result, the included studies were systematic reviews, meta-analyses, control studies and case-series. These studies reviewed contemporary intramedullary nailing as an operative technique in isolation, as well as in comparison to traditional open reduction and internal fixation or plating. Additionally, it reviewed potential consequences of the operative technique. Consequently each of these studies will be critically appraised in this analysis, so that recommendations can be made according to the best available evidence.

Critical Analysis & Discussion
From the literature that was deemed to meet the authors' inclusion criteria, there were eight meta-analysis and systematic reviews within the last five years. Of these all, of the studies addressed mid-shaft clavicle fractures, however all but two specified if the fractures were displaced. Additionally, all studies comparatively reviewed outcomes, but Wijdick *et al.*, 2012 systematic review only addressed complications. Houwert *et al.*, 2011 study was the first of the six to compare plate fixation against intramedullary nailing for displaced mid-shaft clavicle fractures (DMCF). It reviewed one high-quality study and three low-quality studies and assessed functional outcomes. Of the studies, the high quality study identified 15 patients with plate fixation of a DMCF and 17 with IM nail.

The review was in agreement with a previous report that found that both methods were similar in relation to outcomes and effectiveness in a host of measures.

Furthermore, although both procedures had their advantages and disadvantages, plate fixation was not without wound and healing complications. Intramedullary nailing had the added complication of nail migration requiring removal, as well as one recorded brachial plexus injury, despite offering significant improvements in function, pain, cosmetic result and non-union rates. Of the two low quality studies comparing operative and non-operative treatment increased rates of mal-union (6% and 1%) and non-union (18% and 1%), however the review acknowledges the poor quality of this study as a limiting factor. Nevertheless, it concluded that despite the limited evidence, each operative method was effective in restoring functional outcomes and one is not obviously superior [2].

Indeed, Duan *et al* found similar findings in another 2011 meta-analysis. It searched CENTRAL, Pubmed and EMBase and found four suitable studies from the initial pool of 143. It evaluated IM nailing and plating of mid-shaft clavicle fractures in a group of over 300 clavicle fractures and found no significant differences in regard to outcome for Oxford Shoulder Score, Constant Shoulder Score as well as non-union, infection, hardware failure and removal rates. However, it did report more symptomatic hardware events in plating vs. IM nailing. Limitations for this review were that is only addressed fractures that were displaced and shortened. Additionally, only two of the studies adequately performed allocation concealment in order to avoid selection bias, which is of obvious concern in the clinical setting. Despite this, it did tend to support plating and IM nailing of these injuries, yet recommended more large high quality control-trials to properly assess the two different modalities, as a significant difference between the two was not directly observed or appreciated [3].

Building on this, Zhu *et al* reviewed five studies of high quality over a six-year period following an initial database search that revealed 127 papers. In total, 128 patients underwent plate fixation and 157 underwent IM nail fixation. Zhu compared variables for several factors such as surgery duration; incision length; union time; Constant Score at 12 month review; overall complication rate; superficial infection; symptomatic hardware: and hypertrophic scar formation. Studies report mean times of 37.0 and 64.7 minutes in the IM nail and plate fixation groups respectively, however only two provided standard data form. Incision length was also smaller in the IM nail group (4.3 vs. 8.7 cm), however two studies displayed significant discrepancy and heterogeneity. Union time was slightly shorter in IM nail than plate fixation (20 vs. 25.2 weeks) and the IM nail also showed slightly higher Constant Scores at 12 months (93.8 vs. 89.3) with the pooled results approaching significance without heterogeneity.

Of the complications, IM nailing also had a reduced overall complication rate with an odds ratio of 0.09 with no heterogeneity. It was concluded that despite some minor limitations in blinding and patient selection, IM nailing appeared to be the supeior method of fixation with fewer complications [4]. Xiao *et al* found similar results following strict evaluation of 12 studies. It found at the 6-month stage that IM nail fixation had higher Constant Scores and fewer complications. At the 12 and 24-month mark, functional recovery appeared to be similar in both as well as DASH score questionnaire results at 12 months. Additionally shoulder motion, and complications all appeared to be similar for both groups [5]. Sun *et al* also found that both IF and PF were comparative in outcome with IF associated with shorter time to bone union (MD -0.60 weeks), less surgery time (MD -21.29) in minutes and is thus an attractive alternative [6]. Barlow *et al.*, systematic review did not contribute significantly to the above findings as it stated while they found no difference between the two operative techniques, they did not undertake a meta-analysis due to heterogeneity of the data [7].

Wijdicks *et al* reviewed complications for IF for DMCF in a 2013 study. It found six studies, three of which were graded with the highest level of evidence. It reviewed both major and minor complications and found that major complications occurred in no higher than 7%. Minor complications were reported differently in the three different studies with rates of implant-related irritation rate of 31% resulting in three devices being removed due to superficial wound infection (10%). Device protrusion was reported in 20% of cases. The level II-IV evidence each reported different rates. The level II reported no complications in 35 patients whereas a retrospective cohort study describes various forms of delayed union or non-union and 30% asymptomatic radiographic migration. The one level IV study had a 20% rate of hardware irritation [8].

Hill performed a review of publications comparing IM nailing of DMCF against non-operative treatment. A search of the literature from 1966 until 2014 was performed with thirteen studies identified and after exclusion, three chosen to be critically appraised [9]. Each study demonstrated superior outcomes in various forms of IF of DMCF, however one study included by Judd *et al* did have a higher overall complication rate [10]. Other findings in this study included statistically significantly better shoulder function early and later on, faster time-to-union and fewer non- and delayed union rates [9]. While there were overall positive findings, the review concluded in saying that further research must be done with large samples and reproducible methods. The most recent meta-analysis performed in 2016 by Gao *et al* reviewed PF against IF over the past 20 years. It reviewed randomized controlled trials and non-RCTS comparing the two with 513 patients undergoing IF and 521 with PF. Gao found that across the included studies IF was associated with decreased operative time, hospital stay, wound size and complications where shoulder score and union rate were not different between both groups. It concluded that considering the better performance of IF, it recommended it for DMCF [11].

A further seven studies compared both the IF and PF in multiple aspects using different study methods. While each did not look at the exact same type of IF and PF device they are able to provide a broad review of the methods of fixation and their outcomes. The first two studies reviewed IF and PF prospectively over several years. While both found similar results, a critical difference was the type of intramedullary fixation device. Narsaria *et al* compared elastic intramedullary

nailing against pre-contoured plating in 66 patients with DMCF with subsequent clinical and radiological reviews over two years. Follow up criteria included union time and rate, shoulder and arm function (using ASES and Constant Score), as well as complication information. Other than one episode of non-union (3.03%) and implant failure (3.03%), IM nailing had significantly less complication rates. Additionally, surgery time (40.2 vs. 58.4 minutes), incision length (4.5 vs. 10.2 cm), average stay (1.4 vs. 2.8 days), average blood loss (70ml vs. 130.8ml) and union time (6.1 vs. 7.4 months) were all reduced in the IM group comparatively. Despite this, total Constant and ASES Scores were comparative at the end of the study and the study suggested that elastic IF is a safe alternative to PF in these patients [12]. Comparatively, Zehir *et al* prospectively reviewed 45 patients with either Sonoma CRx Collarbone pin again MIPPO (mini-invasive) plating. Despite the difference in IM device, of which two of the authors (MW and PP) have direct clinical experience, similar findings of less time for theatre, hospital stay and bony union were noted for IF.

Furthermore, DASH scores were noted to be not significantly different between either and as a result the Sonoma CRx Intramedullary pin was also deemed to be a safe alternative [13]. Zehir also completed another study reviewing the outcomes of elastic intramedullary nailing in 17 patients. It demonstrated a mean operative time of 30.4 minutes (range 25-42) and mean union time 15.8 weeks). Other than two implant fractures the fixation method showed a mean Constant Score of 94.3 and mean DASH score of 11.8, both excellent outcomes. Overall it demonstrated that elastic IM IF for non-comminuted clavicle fractures has a high success rate [14].

Further studies comparing the fixation methods also lend support to IF and PF equally. Kwak-Lee *et al* reviewed 101 individuals with acute mid-shaft clavicle fractures and found that while IF had earlier improved short-term results, both had similar excellent results in terms of union and motion in the long term [15]. This was further supported by Braun *et al* who found extremely similar strength measurements, DASH and Constant Score following both IF and PF [16]. Ferran *et al* also concluded that both fixation methods produce good results, but that IF has the theoretical advantage of preserving periosteal bloody supply, but with the additional downside of also occasionally requiring device removal [17]. Elastic IF was reviewed independently by Hartmann *et al* in a small population and was also supported in the fixation of DMCF. Despite four cases of skin irritation, overall they recommended elastic IF in their 15 patients due to excellent functional results [18].

Each fixation method is not without complication. Four publications have attempted to address the issue with two comparing the two outcomes directly. Indeed, Wijdicks *et al* and Wenninger *et al* retrospectively reviewed IF and PF, albeit in different population groups. The latter reviewed 62 active military personnel (33 rigid IF vs. 29 PF) and found that overall complication rate was higher in the PF group (31% vs. 9%). Mostly this extended to symptomatic hardware, however one patient who underwent IF suffered superficial wound infection, which was treated satisfactorily with antibiotics [19]. Wijdicks *et al.*, study found similar trends, however overall higher rates of complications after PF against elastic IF over a five-year retrospective period. In the study, 90 patients (43 PF vs. 47 IF) were found to have higher rates of re-fracture (7.0%), major revision (11.6%) and implant failure (14%) in PF groups, whereas the IF group had rates of 0%, 2.1% and 2.1% respectively [20]. Two further studies have reviewed IF independently. Mudd *et al* reviewed IF with the Rockwood clavicle pin and found 14 complications in 10 of 18 patients. Despite being a small study a disturbingly high percentage of soft tissue and non-union were recorded and the Rockwood pin IF device was not recommended [21]. This was supported by a 2007 review by Strauss *et al* that included three studies which stated despite good fixation by IF, the Hoagie and Rockwood pin produced an unreasonably high complication rate [22].

Conclusion

In recent times in the field of trauma and upper limb Orthopaedics, there has been significant research into the topic of operative fixation of displaced mid-shaft clavicle fractures. Previously, these injuries have largely been treated non-operatively, however in recent times more of them have received operative fixation. From this systematic review, it is possible to suggest that both intramedullary fixation and plate fixation have very positive results in terms of shoulder function scores (DASH and Constance Scores), time-to-union and return to function, as well as few complications. Of the two fixation methods, intramedullary fixation has overall the more positive outcomes in both the short and long term. However, it must be noted that operative fixation is not without risks and that any benefits must be weighed against poor outcomes and specific patient risk factors (such as smoking and poor wound healing and compromised bony union).

There have been several meta-analyses completed recently, however each often examines very few studies and are limited by the heterogeneity of the studies themselves, as well as the lack of level I or II evidence. Of note, recent studies published have been of small sample sizes and thus it is difficult to ascertain the true strength of their results; certainly, based on the lack of strong evidence, clinical decision-making should incorporate clinical experience and judgement. While overall evidence regarding operative fixation is promising, further large multi-centre prospective studies would be beneficial in providing better quality evidence for operative fixation, either intramedullary or plate fixation, against non-operative treatment for mid-shaft clavicle fractures.

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